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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,059	05/22/2000	William J. Curatolo	PC8626BJTJ	2926

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EXAMINER	
DEWITTY, ROBERT M	
ART UNIT	PAPER NUMBER
1616	7

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/577,059	CURATOLO ET AL.	
	Examiner	Art Unit	
	Robert M DeWitty	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17/1/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-76,80-86,93-129,133-139 and 146-148* is/are pending in the application.

4a) Of the above claim(s) *77-79, 87-92, 130-132, 140-145-* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-76,80-86,93-129,133-139 and 146-148* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *77-148* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 77-148 are pending in the instant application.

Claims 77-79, 87-92, 130-132, and 140-145 are withdrawn as being drawn to nonelected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 72, 96, and 125 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the specification has required that sustained release or delayed release embodiments be included in the dosage forms, such as matrix systems, however the above claims do not contain such an element.

Oral pulse carrier?

The above claims have also failed to include limitations to the use of azithromycin included within the dosage form.

2. Claims 72 and 125 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, in claim 72, Applicant has set forth the dissolution rate of the dosage form, but has not stated that the dosage form contains a certain amount of azithromycin, or even if azithromycin is included in the

dosage form. Likewise, claim 125 sets forth the dissolution rate of the dosage form, but applicant has not forth the criteria for the amount of azithromycin contained within the dosage form.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 72-76, 80-86, 93-130, 133-139, and 146-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (U.S. Pat. No. 5,605,889), further in view of Handsfield et al., Urquhart (U.S. Pat. No. 4,851,231), and Edgren (U.S. Pat. No. 4,522,625).

Curatolo teaches a dosage form which can be administered to a mammal. The dosage form can comprise from 25 mg to 3 grams of azithromycin (col. 4, lines 51-54). During in-vitro analysis utilizing USP-2 dissolution apparatus under the conditions of 900ml approx. 0.1 M dibasic sodium phosphate buffer, pH 6.0, 37oC, with paddles turning at 100 rpm, the azithromycin dosage form of Curatolo et al. exhibits 90% dissolution within 15 minutes when an amount of the dosage form is equivalent to 200mg (col. 5, lines 27-35). The tablets can be film-coated with hydroxypropylmethylcellulose (col. 7, line 65-col. 8, line 2).

Handsfield teaches that 2.0 grams of azithromycin treat uncomplicated gonorrhea.

Urquhart teaches that certain drugs such as erthromycin, that induce nausea and vomiting should not be administered to the stomach, but administered to the intestine over time.

Edgren teaches a dispenser for releasing drug formulations, such as in the gastrointestinal tract over a prolonged period of time (col. 3, lines 43-46). The dispenser is comprised of a body having a wall that surrounds an internal compartment, and can be shaped round or capsule. Passageways are included in the dispenser such as apertures, orifices, bores, holes and the like (col. 5, lines 32-34).

One with ordinary skill in the art would have been motivated to use 2 grams of azithromycin in a single dose in order to obtain the beneficial effects of using such a dosage amount (*see* Handsfield). Whereas Curtolo does not disclose the dissolution rate of the drug at 1 hour, 2 hour, 4 hour, etc. and that the dosage form is controlled release, Curatolo does disclose the dissolution time of a 200 mg dosage form, which corresponds to that of the instant invention. Thus, one with ordinary skill in the art would know a suitable dissolution rate for delivery azithromycin (which corresponds to the instant invention). One with ordinary skill in the art would have been motivated to administer a form at the dissolution rate taught by Curatolo to administer the dosage form to the gastrointestine as opposed to the stomach.

Further to the above, the instant invention fails to claim the amount of azithromycin contained within the dosage form.

Response to Arguments

4. Applicant's arguments filed 1/17/02 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, whereas Curatolo does not explicitly state a controlled release or delayed release dosage form, the dosage forms by Curatolo satisfy the dissolution profile of the instant invention (less than 200 mg dissolution in 15 minutes). Applicant has failed to include the amount of azithromycin contained within the dosage form, but rather has claimed the dissolution profile of the dosage form (which may or may not be an extrapolation of a dosage form containing less than 2 grams). Motivation to combine Curatolo with the secondary references arises because one with ordinary skill in the art would desire to obtain a dosage form with sufficient amount of drug (2g) allowing the treatment of disease (gonohorrea) while avoiding the harmful affects associated with drugs that cause nausea and vomiting (this is accomplished by dissolving the drug in the GI tract as opposed to the stomach).

5. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
May 7, 2002

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
1616